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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/551,452 | 09/12/2006 | Yingfu Li | 16554-004US1 | 2999 |

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| EXAMINER | |
|---|---|
| LIU, SUE XU | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1639 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 03/19/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/551,452 | LI ET AL. | |
| | Examiner | Art Unit | |
| | SUE LIU | 1639 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Status*

Claims 16-20 have been added.

Claims 1-20 are currently pending.

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-4, drawn to a method of selecting an aptamer capable of binding to a target.

Group 2, claim(s) 5-8, drawn to an aptamer. (Subject to Further Restriction as discussed below).

Group 3, claim(s) 9-20, drawn to an aptamer selection system comprising various components.

### *Further Restriction (Note: This is not species selection.)*

2. The inventions listed as Group 2 is subjected to further restrictions as set forth below:

A.) Applicants are further requested to select a single specific DNA sequence identified by its corresponding SEQ ID NO. (e.g. SEQ ID No. 4)

(As a result of the "further group restriction", each one of the Group 2 is further restricted into subgroups. Each one of the subgroup would result in one invention drawn to a single SEQ ID NO.)

The "Further Restrictions" are deemed proper since each one of the restrictions would result in a nucleic acid sequence that possesses distinct function and/or structures. The different nucleic acids would not share the same structure (such the same nucleic acid sequence), and would also have different properties (such as encoding for different proteins) and therefore different functions. These different polynucleotides comprise nucleic acids with different sequences and functions. For example, the nucleic acid listed as SEQ ID NO6 and SEQ ID NO10 have different nucleic acid sequences and lengths. These different nucleic acids do not appear share a common core structure and/or function, and thus do not share a single general inventive concept. Therefore, these different nucleic acids lack unity of invention. See MPEP 803.04, MPEP 1850 XIII as well as the Pre-OG Notice (published 3/27/07; signed 2/22/07) rescinding the "partial waiver" for restriction practice regarding sequences.

3. The inventions listed as Groups 1-3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Each group of invention has a different technical feature. For examples, the common feature for the Group 1 invention is an oligonucleotide library; the technical feature of Group 2 is

an specific aptamer; the common feature of Group 3 invention is a system comprising various reagents. Therefore, Groups 1-3 are not so linked by the same or a corresponding special technical feature as to form a single inventive concept. In addition, the special technical feature of Group 1 is known in the prior art. For example, Davies et al (PNAS. Vol 99: 11616-11621; 2002; cited in IDS) teach the screening a library of RNA molecules to isolate an aptamer that binds to a target (See entire document), which the library of RNA molecules read on an oliognucleotide library. Sooter et al. (Biol. Chem. Vol. 382: 1327-1334; 2001; cited in IDS) also teaches screening various libraries of oligonucleotides for isolating aptamers (see Abstact). Similarly, Lin et al (PGPUB 20020037506; 3/28/02 or earlier filing date), also teaches various oligonucleotide libraries as well as the concept of using a bead capture oligonucleotide for screening against a target (e.g. Abstract).

Therefore, the inventions lack unity as demonstrated by showing the common technical feature(s) does not "define a contribution over the prior art" "*a posterior*". See MPEP 1850.

***Species Election***

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicants are requested to further elect **a single ultimate species for <u>each</u>** of the following:

a. A single specific selection of a method either with **<u>OR</u>** without the step of "amplifying the library nucleotides collected". (e.g. claims 2 and 4; For Group 1).

i. If applicants elected a method with the amplification step, applicants are further requested to elected a method either with **OR** without the step of "sequencing clones". (e.g. claim 3; For Group 1).

b. A single specific selection of a "system" either with **OR** without "a first primer binding domain" and "a second primer binding domain" (e.g. claim 10; for Group 3).

c. A single specific selection of a "system" either with **OR** without "a first primer" and "a second primer" (e.g. claim 10; for Group 3).

d. A single specific selection of a "system" either with **OR** without "avidin coated agarose beads". (e.g. claim 14; for Group 3).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. The claims are deemed to correspond to the species listed above in the following manner:

Please see the above species selection for correspondence between the claims and the species selection.

The following claim(s) are generic: 1-20.

The species lack the same technical feature, because they do not share a common core structure and/or function. The different species would also differ in their reactivity and the starting materials from which they are made. For examples, the different species of products can be various compounds, which species do not share the same core structure and do not have the same function. For different species of method, the method steps for each species would differ. Consequently, the species have different issues regarding patentability. Thus the unity of invention between each species subgroup is lacking.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sue Liu/
Patent Examiner, AU 1639
3/14/09